

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulation
Department of Health and Mental Hygiene
(DLS Control No. 15-348)**

Overview and Legal and Fiscal Impact

The regulations authorize a licensed pharmacist to administer a self-administered drug in accordance with a prescription under specified circumstances. In addition, a pharmacy student in a Pharmacy Experiential Program or a registered pharmacy intern may administer a self-administered drug under the direct supervision of a licensed pharmacist under specified circumstances.

The regulations present no legal issues of concern.

There is no fiscal impact on State or local agencies.

Regulations of COMAR Affected

Department of Health and Mental Hygiene:

Board of Pharmacy: Pharmacist Administration of Self-Administered Drugs:
COMAR 10.34.39.01-.05

Legal Analysis

Background

Chapter 447 of 2015 authorized a pharmacist, in accordance with regulations adopted by the Board of Pharmacy, to administer a self-administered drug prescribed by an authorized prescriber.

Summary of Regulations

The regulations authorize a licensed pharmacist to administer a self-administered drug in accordance with a prescription. “Self-administered drug” means a drug that is regularly administered by the patient for whom the drug is prescribed or by an individual who is not authorized to administer drugs under § 12-509 of the Health Occupations Article. A “self-administered drug” includes: (1) eye drops; (2) a drug that is administered by an intramuscular injection or a subcutaneous injection; (3) ear drops; (4) inhalation therapies; (5) intranasal therapies; and (6) topical therapies. A licensed pharmacist is required to attest that the pharmacist has the appropriate training in administration of self-administered drugs that consists of instruction on ear drops, eye drops, inhalation therapies, intramuscular injections, intranasal therapies,

subcutaneous injections, and topical therapies. A licensed pharmacist is deemed to have satisfied the training requirements. In addition, a licensed pharmacist is required to possess an active certification in basic cardiopulmonary resuscitation obtained through in-person classroom instruction.

In addition, a pharmacy student in a Pharmacy Experiential Program or a registered pharmacy intern may administer a self-administered drug under the direct supervision of a licensed pharmacist who meets the specified training requirements and has cardiopulmonary resuscitation certification.

A pharmacist is required to document in the patient record the administration of a self-administered drug, including the following information: (1) name of the drug; (2) dosage administered; (3) site of administration; (4) date and time of administration; and (5) any instructions provided to the patient. The patient record is required to be maintained for five years, unless otherwise required by law. In addition, the patient record is required to be readily retrievable and made available on the request of the board.

Legal Issues

The regulations present no legal issues of concern.

Statutory Authority and Legislative Intent

The Department of Health and Mental Hygiene cites §§ 12-101, 12-102(b), and 12-509 of the Health Occupations Article as statutory authority for the regulations. Section 12-101 defines terms. Section 12-102(b) provides that specified provisions of law do not limit the right of an individual to practice a health occupation that the individual is authorized to practice under the law. Section 12-509 authorizes a pharmacist to administer a self-administered drug to a patient that is prescribed by an authorized prescriber.

This authority is correct and complete. The regulations comply with the legislative intent of the law.

Fiscal Analysis

There is no fiscal impact on State or local agencies.

Agency Estimate of Projected Fiscal Impact

The regulations implement Chapter 447 of 2015 (House Bill 657), which authorizes a licensed pharmacist, in accordance with regulations adopted by the State Board of Pharmacy, to administer a self-administered drug (*i.e.*, eye drops, ear drops, inhalation therapy) prescribed by an authorized prescriber. The regulations specify that a pharmacist must attest to appropriate training, possess an active certification in cardiopulmonary resuscitation, and maintain certain

records. The department advises that the regulations have no impact on State or local governments. The Department of Legislative Services concurs.

Impact on Budget

There is no impact on the State operating or capital budget.

Agency Estimate of Projected Small Business Impact

The department advises that the regulations have minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs, noting that any potential impact has already been accounted for in the fiscal and policy note for House Bill 657.

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